IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG and TAKEDA PHARMACEUTICALS AMERICA, INC.,	)	C.A. No. 18-88-LPS CONSOLIDATED
Plaintiffs,	)	**REDACTED - PUBLIC VERSION**
v.	)	
APOTEX INC., et al.,	)	
Defendants.	)	

LETTER TO THE HONORABLE JENNIFER L. HALL FROM MEGAN E. DELLINGER SEEKING RELIEF REGARDING PROTECTIVE ORDER DISPUTES RELATED TO DEFENDANTS EXPERT DR. ANTHONY J. ROTHSCHILD

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Dear Judge Hall:

Plaintiffs H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. (collectively, "Plaintiffs") respectfully submit this letter pursuant to the Court's March 5, 2020 Oral Order (D.I. 699).

This is a Hatch-Waxman case arising from the submission of Abbreviated New Drug Applications seeking to market a generic version of Plaintiffs' Trintellix® (vortioxetine) product by Defendants Prinston Pharmaceuticals Inc. and Zhejiang Huahai (collectively, "Prinston"), Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively, "Sandoz"), Unichem Laboratories, Limited ("Unichem"), and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, "Zydus"). Trintellix® (vortioxetine)[1] was developed by scientists at Lundbeck and is marketed by Lundbeck and Takeda.

Defendants have retained Dr. Anthony J. Rothschild as an expert in this matter. Plaintiffs object to Dr. Rothschild obtaining access to materials designated as Confidential Information under the Protective Order and serving as an expert witness for Defendants because of confidential relationships between Plaintiffs and Dr. Rothschild.

This Court Should Preclude Defendants from Using Dr. Rothschild as an Expert.

Expert disqualification may be warranted when "a party retains expert witnesses who previously worked for an adversary and who acquired confidential information during the course of their employment." *Eastman Kodak Co. v. AGFA–Gevaert N.V.*, 2003 WL 23101783, at *1 (W.D.N.Y. Dec. 4, 2003). This Court considers two factors for expert disqualification: (1) "was it objectively reasonable for the first party who claims to have retained the expert to conclude a confidential relationship existed" and (2) "was any confidential or privileged information disclosed to the expert?" *Merck Sharp & Dohme Corp. v. Teva Pharm. USA, Inc.*, 2015 WL 5163035, at *2 (D. Del. Sept. 3, 2015). Courts also consider the public interest. *See id.*

A. Multiple Confidential Relationships Were Formed Between Plaintiffs and Defendants' Expert Dr. Rothschild

Multiple confidential relationships between Plaintiffs and Dr. Rothschild existed during which Dr. Rothschild was exposed to confidential material.

First, Dr. Rothschild served as a Principal Investigator and participated extensively in multiple clinical studies involving vortioxetine that were sponsored by Plaintiffs and submitted to FDA as part of the New Drug Application for Trintellix®(vortioxetine).[2] *See, e.g.*, [redacted]; Ex. 2 (FDA Statement of Investigator for LuAA21004_310); Ex. 3 (Clinical Study Report for LuAA21004_310); [redacted] Dr. Rothschild is listed as an author (together with Takeda employees) on at least one publication resulting from these studies. *See* Ex. 7 (July 20, 2012 European Neuropsychopharmacology Article). However, much of the information generated from and by these

[1] Trintellix® contains vortioxetine hydrobromide as its active ingredient and is approved by the U.S. Food and Drug Administration for the treatment of major depressive disorder in adults.

[2] Dr. Rothschild's involvement in these studies is readily apparent from documents produced by Plaintiffs prior to Defendants' disclosure of Dr. Rothschild as their expert.

clinical studies and known to Dr. Rothschild remains confidential even after publication of a subset of the results.

In connection with his clinical research on Trintellix®, Dr. Rothschild had access to proprietary data and information about Plaintiffs' clinical development program, including research data, commercial information, and publication strategy. Specifically, Dr. Rothschild obtained knowledge of Plaintiffs' clinical trial strategy and methodologies and non-published clinical data that could form the basis to study other medical uses of Trintellix® (vortioxetine). Disclosure of this kind of confidential information would likely cause substantial harm to Plaintiffs' competitive position within the pharmaceutical industry given the research-intensive nature of these companies. Moreover, these clinical studies are central to the patent infringement contentions in this case because Defendants have disputed infringement of several method of treatment patents asserted in this case: United States Patent Nos. 9,278,096 ("the '096 patent") (all Defendants); 9,125,910 ("the '910 patent") (all Defendants); and 8,476,279 ("the '279 patent") (Zydus and Sigmapharm).

In the context of this relationship, Dr. Rothschild and Takeda [redacted] Dr. Rothschild's involvement with Plaintiffs' clinical development program and his corresponding exposure to confidential information is directly at odds with his service as an expert or consultant for Defendants in this case. Even worse, Dr. Rothschild's work was on clinical studies on the same product central to this litigation, which presents an unavoidable risk that Dr. Rothschild would inadvertently violate his obligations to Plaintiffs, including comingling previously received information with this matter.

Second, Dr. Rothschild was engaged by Plaintiff Lundbeck as a consultant and expert in U.S. litigation related to Lexapro® (escitalopram) and Celexa® (citalopram), including *Forest Labs. v. Caraco Pharm. Labs.*, 2:06-cv-13143 (E.D. Mich.), *Infosint SA v. H. Lundbeck*, 1:07-cv-06525 (S.D.N.Y.), and *Forest Labs. v. Ivax Pharm.*, 1:03-cv-00891 (D. Del.). Lexapro® and Celexa® are antidepressants that were developed and marketed by Plaintiff Lundbeck before Trintellix®.

In the Lexapro® and Celexa® litigations, Dr. Rothschild worked with Lundbeck and its outside counsel and was exposed to confidential and privileged information related to Lundbeck's proprietary technologies and IP strategy for Lundbeck's antidepressants, as well as Lundbeck's internal operations relating to the research, development, and commercialization of antidepressants. Lexapro® (escitalopram) and Celexa® (citalopram) are relevant to infringement and validity in this case. Indeed, the label for Trintellix® (vortioxetine) includes head-to-head clinical study data comparing vortioxetine to escitalopram with respect to treatment-emergent sexual dysfunction (TESD). This study is at the center of the parties' infringement dispute regarding the '096 Patent. Moreover, Defendants are using publications discussing the effects of these antidepressants as prior art references in arguing invalidity of the patents-in-suit. Ex. 9 (Invalidity Contentions) at 17, 19, 69, 166, 173, 179.

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[3] [redacted]

"Courts have been quick to find a confidential relationship in situations where the expert witness previously worked for the opposing party." *Thompson, I.G., L.L.C. v. Edgetech JG., Inc.*, 2012 WL 3870563, at *4 (E.D. Mich. Sept. 6, 2012). Here, such knowledge of Plaintiffs' confidential material from other litigations in the same subject matter (antidepressants) is disqualifying and presents a risk of comingling previously received information with this matter. *See, e.g., Auto-Kaps, LLC v. Clorox Co.*, 2016 WL 1122037, at *2–4 (E.D.N.Y. Mar. 22, 2016) (disqualifying expert and noting that exposure to confidential information relating to the moving party's IP strategy is relevant as such information may inadvertently affect his analysis).

B. Disqualification of Dr. Rothschild Promotes Fairness and Integrity Without Any Significant Prejudice to Defendants

There can be no dispute that there exist multiple prior confidential relationships between Plaintiffs and Dr. Rothschild and confidential information was disclosed to Dr. Rothschild pertaining to relevant issues in this matter. Therefore, knowledge of confidential information from these prior relationships covering the same drug, Lundbeck's prior antidepressants, and litigation strategy risk comingling with Dr. Rothschild's analysis and opinions reached in this litigation on the same subject matter. Where such risk exists, this Court has disqualified experts to prevent even the accidental disclosure or use of confidential information. *See, e.g.*, Ex. 10, *MorphoSys AG v. Janssen Biotech Inc.*, No. 16-221-LPS (D.I. 178). Similarly, other courts have also disqualified such experts. *See, e.g.*, *Auto-Kaps, LLC v. Clorox Co.*, 2016 WL 1122037, at *5 (E.D.N.Y. Mar. 22, 2016) ("The court must therefore protect the integrity of the judicial process by ensuring that experts do not use, even unwittingly, confidential information that they learned from a party in the course of an earlier engagement against that party in a later lawsuit."); *WesternGeco LLC v. Ion Geophysical Corp.*, 2010 WL 2266610, at *1–2 (S.D. Tex. June 2, 2010); *Oracle Corp. v. DrugLogic, Inc.*, 2012 WL 2244305, at *7 (N.D. Cal. June 15, 2012); *Pellerin v. Honeywell Int'l Inc.*, 2012 WL 112539, at *3 (S.D. Cal. Jan. 12, 2012).

Defendants assert that just because someone had Plaintiff's confidential information in his head, that does not prevent him from being retained as Defendants' expert, citing *Cephalon, Inc. v. Sun Pharm. Indus., Inc.*, 2013 WL 4609570, at *1 (D.N.J. Aug. 29, 2013). That is not the correct standard, and *Cephalon* is a red herring. The decision in *Cephalon* did not involve a motion to disqualify an expert witness and in fact, involved seeking discovery from a fact witness. And, as articulated above, the correct standard merely requires establishing that a confidential relationship existed with Dr. Rothschild and that confidential information was disclosed to him. Given the confidential relationship related to clinical studies and prior litigations covering the exact same subject matter established between Dr. Rothschild and Plaintiffs and in effect today, Dr. Rothschild should be precluded from serving as an expert for Defendants in this matter.

In determining whether Defendants will suffer prejudice from disqualifying their expert, the Court can consider "whether another expert is available and whether the opposing party will be unduly burdened by having to retain a new expert." *Hewlett–Packard Co. v. EMC Corp.*, 330 F. Supp. 2d 1087, 1095 (N.D. Cal. 2004). Defendants have disclosed many other, non-objected-to technical experts that may be able to testify in lieu of Dr. Rothschild. Defendants have made no showing that another expert with similar qualifications is not available. The risk of Dr. Rothschild's involvement in this case far outweighs any prejudice to Defendants.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)